### IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

LIFEWATCH SERVICES, INC. and CARD GUARD SCIENTIFIC SURVIVAL, LTD.,

**Plaintiffs** 

V.

BRAEMAR, INC, ECARDIO DIAGNOSTICS, LLC, and MEDNET HEALTHCARE TECHNOLOGIES, INC.,

Defendants.

Case No.: 09CV6001

Hon. William J. Hibbler, U.S.D.J. Hon. Arlander Keys, U.S.M.J.

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

#### INTRODUCTION

LifeWatch's opposition demonstrates why summary judgment of noninfringement should be entered in Defendants' favor. Defendants established in their motion for summary judgment that the Accused Products do not infringe because the relevant claims require a long-term storage means capable of continuously recording twelve hours or more of ECG data and the Accused Products are capable of recording no more than thirty minutes' of ECG in maximum increments of five minutes. By proposing a wholly different definition of "long term storage," LifeWatch tacitly concedes that if "long term" refers to the quantity of data retained in the long term storage means, as measured in hours, then summary judgment is appropriate.

In their motion for summary judgment, Defendants identified a wealth of intrinsic evidence showing that the long term storage required by the '143 Patent must have the capability of recording at least twelve hours of continuous ECG data. To that end, the '143 Patent specification, on which the Federal Circuit relies as the "best source" of meaning, *see infra* at 3-

- 4, includes the following statements that make clear that "long term storage" refers to data storage having the capacity of recording at least twelve hours of ECG data:
  - "The monitor includes a separate long-term memory for storing up to 12-24 hours of data which can also be down loaded." Patent, Abstract;
  - "The monitor of the present invention also includes a separate long-term memory for storing more data, hours before and/or after the trigger event, e.g., 12-24 hours or more additional data which can also be downloaded." Patent, Col. 2, lines 31-34;
  - The invention's transtelephonic unit "may also permit the downloading of some or all data from the 12-24 hour long-term memory." Patent, Col. 4, lines 44-47;

The specification emphasizes the invention's capability of recording continuous ECG data as part of its purpose to combine the benefits of both Holter type and event type cardiac monitors:

- "[T]his invention relates to a wearable device for the selective and continuous recording of electrocardiographic data." Patent, Col. 1, lines 6-7;
- "The present invention is directed to an electrocardiographic monitoring and recording device that includes the continuous long term recording of a Holter device and the selective recording of event type records." Patent, Col. 2, lines 13-16;
- "Simultaneously with the selective recording, continuous extended recording occurs, allowing for 24 hours or more of ECG data to be captured for evaluation [of] all or any portion." Patent, Col. 1, lines 13-16;
- "The present invention is directed to overcoming the shortcomings of both Holter type and event type cardiac monitors." Col. 2, lines 7-9; see also Patent, Background of the Invention, at Col. 1, line 18 Col. 2, line 39 (describing the invention as an improvement over the prior art, consisting of electrocardiographic monitoring devices that functioned either as Holter type recorders or selective recorders, because the invention could serve as both).

In response, LifeWatch has failed to identify even one reference from either the Patent or its prosecution history that supports its claim interpretation. Instead, faced with such a clear record, Plaintiff's opposition resorts to a litigation-induced construction that ignores the plain language of the Patent and the very purpose of the claimed inventions, relying instead on extrinsic evidence in the form of dictionary definitions and a purported expert from an entirely

different field. LifeWatch's attempt to elevate extrinsic evidence over the intrinsic evidence is directly contrary to well-established precedent regarding patent claim construction and should be rejected as a matter of law.

Because the declaration of LifeWatch's expert is, by itself, sufficient to show that he is not a person of ordinary skill in the relevant art, that declaration is entitled to no weight. The intrinsic evidence is, by itself, more than sufficient to grant judgment of noninfringement. However, to the extent the Court believes it appropriate to consider extrinsic evidence, Defendants have submitted the expert witness declaration of Dr. Robert Schwarzberg, the sole inventor of the '143 Patent. As that declaration shows, Dr. Schwarzberg clearly is a person of ordinary skill in the art of the '143 Patent claims and his opinion only lends further support to the commonsense reading of the specification advocated here by Defendants.

#### **DISCUSSION**

- I. The Specification Requires Long Term Memory To Be Able To Store At Least Twelve Hours of Continuous ECG Data
  - A. LifeWatch Advocates an Interpretation of the Claim that is Contrary to the Specification

Any attempt by LifeWatch to interpret the '143 Patent claims in a manner contrary to the Patent's specification should be rejected out of hand. As the Federal Circuit has observed, "This court and its predecessors have long emphasized the importance of the specifications in claim construction." *Philips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005)(citations omitted). The Federal Circuit has described the specification as "the **best source** for discerning the proper context of claim terms." *Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004)(emphasis added); *see also Phillips*, 415 F.3d at 1315; *Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998). Where the specification

describes a fundamental feature or purpose of an invention, the claims must be read in a manner that furthers that fundamental feature or purpose. *Praxair, Inc. v. Atmi, Inc.*, 543 F.3d 1306, 1324 (Fed. Cir. 2008) ("The claims of the patent must be read in light of the specification's consistent emphasis on this fundamental feature of the invention."); *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1364 (Fed. Cir. 2001) (affirming claim construction that was consistent with and in furtherance of the purpose of the invention"); *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1160 (Fed. Cir. 1997)("In construing claims, the problem the invention was attempting to solve, as discerned from the specification and the prosecution history, is a relevant consideration.")

As discussed in Defendants' opening brief in support of summary judgment, the '143 Patent specification is replete with references that demonstrate that "long term," as used in the phrase "long term storage means" refers to the amount of continuous data recorded – a quantity measured by time. In contrast, there are no such references to support LifeWatch's contention that "long term" refers to the length of time for which the data may be stored. The specification uses the terms "storage" and "recording" interchangeably. *See, e.g.,* Patent, Col. 2, lines 13-16; Col. 2, lines 31-34. The specification consistently refers to long term recording as distinguished from selective recording and describes the combination of continuous long term (i.e. "Holter type") monitoring and selective recording in a single device as the central feature of the invention. *See,* Patent, Col. 2, lines 13-16 ("The present invention is directed to an electrocardiographic and monitoring and recording device that includes the continuous long term recording of a Holter device and the selective recording of event type records."); Patent, Col. 1, lines 13-16 ("Simultaneously with the selective recording, continuous extended recording occurs, allowing for 24 hours or more of ECG data to be captured for evaluation [of] all or any

portion."). The specification describes the invention as an improvement over the prior art, consisting of electrocardiographic monitoring devices that functioned as either Holter type recorders or selective recorders, because the invention could serve as both. *See* Patent, Background of the Invention, at Col. 1, line 18 – Col. 2, line 39.

In an unjustifiable effort to persuade the Court to adopt its preferred claim construction, LifeWatch mischaracterizes the specification language.

LifeWatch's Characterization of the Specification	What the Specification Actually Says
"The monitor device of the invention also includes a long-term memory for storing data	"The monitor device of the present invention also includes a separate long term memory <i>for</i>
for an extended period, before and/or after the	storing more data, hours before and/or after
trigger event,"	the trigger event, e.g., 12-24 hours or more of additional data, which can also be
See Pls. Stmt of Add'l Facts, ¶ 4, purporting to cite Col. 2, lines 31-34	downloaded."
(emphasis added).	See Col. 2, lines 31-34 (emphasis added).

Contrary to LifeWatch's assertions, the lines of the specification that LifeWatch cites make no reference whatsoever to storing data *for an extended period*, but instead describes the long term memory in terms of the quantity of data stored measured by time (*i.e.*, "hours before and/or after the trigger event"), *not* the storage duration.

LifeWatch contends that the Court's construction should be based on the ordinary and customary meaning of "long term storage." See Pls. Memo. in Opp. at 8-9. As the Federal Circuit has emphasized, however, a construction cannot be based on a claimed "ordinary and customary" meaning where the patent itself discloses that the term is given a specific meaning in the context of the patent itself. *See, e.g., Phillips*, 415 F.3d at 1316 ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess."); *see also Alloc, Inc. v. International Trade* 

Commission, 342 F.3d 1361, 1367 (Fed. Cir. 2003)("A patent applicant may consistently and clearly use a term in a manner either more or less expansively than its general usage in the relevant art, thereby expanding or limiting the scope of the term in the context of the patent claims."); C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 363 (Fed. Cir. 2004) (rejecting the patentee's reliance on dictionary definitions where the intrinsic evidence demonstrated a different meaning). Similarly here, LifeWatch's claimed ordinary and customary meaning cannot trump the contrary intrinsic evidence of the specification.

B. The Specification Requirement That Long Term Memory Be Capable Of Recording At Least Twelve Continuous Hours Of ECG Data Is Found In Descriptions Of The Invention As A Whole, Not Just In Preferred Embodiments.

In a further attempt to avoid the incontrovertible evidence that establishes that "long term" refers to the quantity of data recorded by the long term storage means, LifeWatch denigrates these references as mere descriptions of a preferred embodiment. Memo in Opp. to Summary Judgment at 11-12. This argument ignores the fact that many of the references are found, not in the section of specification that describes the preferred embodiment, but rather, in the portions of the specifications that describe the invention as a whole.

The Federal Circuit has ruled that statements in the specification that describe the invention as a whole are more likely to support a limiting definition of a claim term. To that end, in *C.R. Bard*, the court construed a patent relating to a mesh plug used to repair hernias. The specific construction issue concerned whether the claim at issue required that the plug have a "pleated surface." Although the specific claim at issue referred to a "conformable" and "pliable," rather than a pleated, plug, the court relied on two "statements of general applicability" contained in the Summary of Invention and the Abstract: "In two places, the patent describes in general terms what it deems to be the invention. In both places, the patent unequivocally defines the

claimed plug as having pleats." 388 F.3d at 864. The court gave these statements dispositive weight in its interpretation of the claim, noting, "Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term." 388 F.3d at 864 (citation omitted). *See also, On Demand Machine Corp. v. In-Gram Indus., Inc.*, 442 F.3d 1331, 1343-44 (Fed. Cir. 2006) (holding specification preamble limited claim where the preamble "states the framework of the invention").

Here, LifeWatch offers no evidence to support its argument that the specification references relied on by Defendants in support of their construction of "long term storage" concern only a preferred embodiment of the invention. A review of the specification shows this is plainly not the case. Those references do not relate merely to "illustrative examples." They describe not only the general character of the invention, but also the very functionality of the invention that distinguishes it from the prior art. The combination of continuous long term recording (Holter monitoring) and selective recording (event recording) is not merely a preferred embodiment of the invention, it is the essence of the invention. Reading the claim as LifeWatch urges would effectively read the limitation providing for continuous long term recording out of the invention.

LifeWatch's proposed construction is also contrary to the "means plus function" nature of the claim, which refers to a "long term storage means for storing signals representative of the heart rhythms of the patient." The use of this "means for" language creates a presumption that this is a "means plus function" limitation subject to 35 U.S.C. § 112, ¶ 6. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1361 (Fed. Cir. 2000). As such, the claim covers only the corresponding structure or its equivalent **in the specification** of the '143 Patent. U.S.C. § 112, ¶

6. Once a court establishes that a means-plus-function limitation is at issue, "it must then construe the function recited in that claim and determine what structures have been disclosed in the specification that correspond to the means for performing that function." *Kemco Sales*, 208 F.3d at 1361. In order to infringe, the accused device must employ "structure identical or equivalent to the structure disclosed in the patent" that "performs the identical function specified in the claim." *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1350 (Fed. Cir. 1999).

The specification has only a single figure, FIG. 1, which identifies the structural elements of the invention. That figure includes a box labeled "Long Term" with the accompanying reference number 22. The description of Figure 1 in the specification identifies the structure indicated by reference number 22 as the long term memory. *See* Patent, Col. 3, lines 6-8 ("In the drawing the memories are represented by evaluation buffer 20 and long-term memory 22, respectively."). The specification also requires that the structure identified by reference number 22 have the ability to store 12 to 24 hours of heart rhythms of the patient. To that end, the specification describes the ability to download "some or all data from the 12-24 hour long-term memory 22." Patent, Col. 4, lines 46-47. In light of the "means plus function" nature of the claim, these structural descriptions cannot be dismissed as a mere "preferred embodiment," but instead control the construction of the term "long term storage."

# II. If Extrinsic Evidence Is Considered, The Declaration Of Dr. Robert Schwarzberg, A Person Of Ordinary Skill In The Art, Supports Defendants' Construction Of The '143 Patent.

As noted above, extrinsic evidence need not be considered in claim construction when the patent itself provides sufficient direction for construction. In this case, if extrinsic evidence is consulted, the relevant extrinsic evidence is that presented by the inventor Dr. Schwarzberg, and not that presented by LifeWatch.

#### A. LifeWatch's Extrinsic Evidence Is From The Wrong Art

LifeWatch's evidence regarding the ordinary and customary meaning of "long term storage" is, on its face, insufficient to create a disputed issue of material fact. It is well-accepted that the claims of a patent are to be interpreted in the way a person of ordinary skill in the art would have understood those terms at the time of the invention. *Phillips*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). In constructing the hypothetical person of ordinary skill in the art, the court is to consider the educational level of the inventor, the type of problems encountered in the art, the prior art solutions to the problem, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of workers in the field. Helifix Ltd. v. Block-Lok, Ltd., 208 F.3d 1339, 1347 (Fed. Cir. 2000). In determining what is the relevant "art," courts have focused on the knowledge most directly related to the problem addressed by the invention. See Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 716 (Fed. Cir. 1991) ("The relevant art 'is defined by the nature of the problem confronting the would-be inventor.") (citations omitted); Minerals Technologies, Inc. v. Omvg AG, 430 F.Supp.2d 195, 208-09 (S.D.N.Y. 2006) (for a patent related to papermaking technology, person of ordinary skill in the art would have skill in the specialized field of papermaking rather than the general field of chemistry); Cargill, Inc. v. Sears Petroleum & Transport Corp., 334 F.Supp.2d 197, 215-16 (N.D.N.Y. 2004)(for a patent related to a roadway de-icing compound, person of ordinary skill in the art would have experience in the field of roadway ice management, rather than extensive experience in chemistry).

LifeWatch fails to even attempt to meet the applicable legal standard with respect to its purported expert, Dr. Sacredoti. Although Dr. Sacredoti describes the relevant art as "portable, wearable electronic devices for recording and transmitting electrocardiographic data," Sacredoti

Decl. ¶ 13, he offers no evidence that he is, in fact, a person of ordinary skill in that art. To the contrary, Dr. Sacredoti's C.V. recites that he is "an internationally known expert in Artificial Intelligence, and can speak and write with authority about many advanced software technologies." Sacredoti Decl., Ex. A, at p. 4. Dr. Sacredoti's experience in the general field of medical devices appears to be limited to working from 1992 to 1993 as the Chief Operating Officer of a medical device company. Dr. Sacredoti does not describe the devices produced by that company and there is no evidence that he has any level of experience or expertise in the design and development of portable cardiac monitoring devices. Dr. Sacredoti's experience is in the field of computer software and not in the art that even Dr. Sacredoti acknowledges is relevant to this case.

Given that there is no evidence upon which the Court can conclude that Dr. Sacredoti is a person of ordinary skill in the art relevant to the '143 Patent, his assertions about the ordinary and customary meaning of "long term storage" – which are based on his background in the area of computer software, not ECG monitors – are entitled to no weight and should be disregarded.

# B. Dr. Schwarzberg Is A Person Of Ordinary Skill In The Art And His Opinion Is Consistent With The Specification

Relevant extrinsic evidence, on the other hand, has been provided by the inventor of the '143 Patent, Dr. Robert Schwarzberg. Defendants' Response to Plaintiff's Rule 56.1 Statement of Facts, ¶ 20. Dr. Schwarzberg is a Board-certified cardiologist who was the chief medical officer of LifeWatch for many years and has been involved in the design of cardiac monitoring devices. *Id.* He is clearly a person of ordinary skill in the art with respect to the '143 Patent. *Id.*<sup>1</sup>

Dr. Schwarzberg's declaration is not offered as the inventor's testimony about what he meant in the patent, but rather, in direct response to LifeWatch's assertions regarding the ordinary and customary meaning of the term "long term storage," as a person of ordinary skill in the art would understand that term. See Howmedica Osteonics

Dr. Schwarzberg states in his Declaration that the invention of the '143 Patent was to combine together a cardiac event recorder with a long term memory like that of a Holter monitor which has the capacity to record many hours of continuous electrocardiographic data recorded from the patient's heart rhythms ("ECG data"). *Id.* In his review of the '143 Patent, Dr. Schwarzberg notes that the novelty in the '143 invention was combining together in one device the benefits one would gain from an event recorder, with the benefits one gains from having a record of long periods of continuous ECG data from the patient's heart. *Id.* In this way, the patient's medical team is alerted to arrhythmias, but can also see what is happening during the intervals between the arrhythmia occurrences. *Id.* According to Dr. Schwarzberg, the "long" in "long term storage" refers to an amount of data measured by the length of time the data is collected, not how long the data is stored. *Id.* 

From his review of the '143 Patent, Dr. Schwarzberg concludes that "long term storage" in claim 18 of the '143 Patent refers to the capability of extended memory reflecting longer recordings of continuous ECG data, i.e. storing 12 hours or more of continuous ECG data of the patient. *Id.* Thus, if any extrinsic evidence is considered on this motion, it should be in the form of the opinions of Defendants' expert, Dr. Schwarzberg, and not any of LifeWatch's extrinsic evidence.

## III. LifeWatch Has Offered No Evidence Contesting The ER920W's Noninfringement.

It remains undisputed that the ER920W is incapable of recording more than five minutes of continuous ECG Data and no more than thirty minutes of non-continuous ECG Data.<sup>2</sup> Unlike

Corp. v. Wright Medical; Technology, Inc., 540 F.3d 1337, 1347 and fn 5 (Fed. Cir. 2008) (Although inventor's testimony may not be used to change the scope of the claim, "[t]he testimony of an inventor, of course, may be pertinent as a form of expert testimony, for example, as to understanding the established meaning of particular terms in the relevant art.")

LifeWatch attempts to argue that the ER920W is more than an event recorder because defendant eCardio uses a "Holter monitoring" reimbursement code for the eVolution (which is identical to the ER920W for purposes of this case). Pls. Mem. at 6. This argument is baseless as the reimbursement code used by eCardio (CPT No. 93236)

the invention of the '143 Patent, which has the capability of providing continuous recording and event recording, the ER 920W is strictly an event recorder. LifeWatch argues that the "FLASH" memory in the ER920W's Event Storage Buffer is a long term storage means. *See* Pls. Memo. in Opp. at 2. It is undisputed, however, that the ER920W's "FLASH" memory, however, has only 30 minutes of capacity, only a small fraction of the twelve hours of long term storage required by the Asserted Claims. Pls. Response to Stmt. of Undisputed Facts, ¶ 48. Moreover, the "FLASH" receives, at most, five minutes of continuous data, as that is the limit in size of the evaluation buffer's SRAM loop from which data is copied to send to the "FLASH." *See* Pls. Response to Stmt. of Undisputed Facts, ¶ ¶ 48, 49.

Nor does the ER920W infringe under the doctrine of equivalents. The test most commonly applied by the courts under the doctrine of equivalents analyzes whether the element performs substantially the same "function" in substantially the same "way" to obtain substantially the same "result" as the claim limitation. *Schoell v. Regal Marine Industries, Inc.*, 247 F.3d 202, 1209-10 (Fed. Cir. 2001); *Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1016 (Fed. Cir. 1998).

No equivalence exists in this case on "long term storage means" under the "function-way-result" test. The '143 Patent's long term storage "functions" as a Holter monitor with many hours of continuous data recorded – the ER920W does not; rather, it "functions" only as an event recorder. The '143 Patent's "way" of achieving long term storage is to send continuous ECG data to a separate memory structure – the ER920W does not send a separate stream of data to a long term memory. *See* SoF, ¶¶ 36-37; Pff's Response to Stmt. of Undisputed Facts ¶ 55 (fact disputed only to the extent "irrelevant"). The '143 Patent's long term storage "results" in the

is for non-continuous recording of data based on 24-hour monitoring looking for arrhythmia. (Defendants' Response to Plaintiff's Rule 56.1 Statement of Additional Facts,  $\P$  19). That code is for monitoring a patient over a long period of time, not continuously recording the patient's ECG data over time as required by the '143 patent. *Id.* 

transmission of twelve or more hours of continuous ECG data to the remote site for analysis – the ER920W is incapable of sending more than thirty minutes of data, only five minutes of which can be continuous data. *See* Pls. Response to Stmt. of Undisputed Facts. Thus, LifeWatch has no basis to rely on the doctrine of equivalents to maintain a claim of long term storage with respect to the ER920W.

#### **CONCLUSION**

For the foregoing reasons, Defendants respectfully request that their motion for summary judgment of noninfringement be granted.

Date: August 10, 2010

#### /s/ John L. Krenn

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